UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,424	03/13/2007	Ronald D. Berger	62270(71699)	5433

49383 7590 09/14/2010

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
SCOTT, AMANDA L	

ART UNIT	PAPER NUMBER
3739	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,424	BERGER, RONALD D.	
	Examiner	Art Unit	
	Amanda Scott	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,15,26-31,37-41,46-49,57-60,65-68 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,15,26-31,37-41,46-49,57-60,65-68 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to because the numbers in the drawings are hand written and are hard to read. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 31 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 is written as a dependent claim but does not state any claim dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 15, 26-31, 37-41, 46-49, 57-60, 65-68, and 73 are rejected under 35 U.S.C. 102(B) as being anticipated by Lesh (US 5,971,983).

Regarding claim 1, Lesh discloses a catheter device comprising an elongated body member having a distal portion (12) and a deflection mechanism operably coupled to the distal portion so as to cause the distal portion to deflect with respect to a longitudinal axis of the elongated body member (view figures 3-8), wherein the catheter

device further includes: a guide member (3,4); a guiding mechanism (13) coupled to the elongated body member and configured so as to guide the guide member; and wherein the guiding mechanism includes an exit portion from which the guide member exits when the guide member is being deployed from the guiding mechanism, where the exit portion is disposed with respect to the distal portion so the distal portion deflects from and with respect to the guide member, when the guide member is in deployed condition (view figures 3-8, column 10, line 45- column 11, line 67).

Regarding claim 9, Lesh discloses the catheter device of claim 1, wherein the guiding mechanism comprises an artifact (30,40) on the external surface of the elongated body member and extending axially along the elongated body member, where the artifact and the guide member are configured and arranged so the guide member is moveably retained by the artifact and so as to allow for deployment of the guide member (column 10, lines 53-67).

Regarding claim 15, Lesh discloses a catheter device comprising an elongated body member having a distal portion (12) and a deflection mechanism operably coupled to the distal portion so as to cause the distal portion to deflect with respect to a longitudinal axis of the elongated body member (view figures 3-8), wherein the catheter device further includes: a guide member (3,4); a guiding mechanism (13) coupled to the elongated body member and configured so as to guide the guide member; an ablation device (20) being disposed in the distal portion, the ablation device being configured and arranged to ablate tissues proximal the ablation device; wherein the guiding mechanism includes an exit portion from which the guide member exits when the guide

member is being deployed from the guiding mechanism; wherein the exit portion is disposed with respect to the distal portion so the distal portion deflects from and with respect to the guide member, when the guide member is in deployed condition; wherein the exit portion is configured and arranged so that the distal portion when in a deflected condition is rotatable about the guide member, when the guide member is in a deployed condition (view figures 3-8 and 16-19, column 24, line 55- column 25, line 20).

Regarding claim 26, Lesh discloses a method for ablating tissue in particular atrial tissue, comprising the steps providing a deflection catheter device that includes a deflectable distal portion (12), an ablation device (20) disposed within the deflectable distal portion and a guide member (3,4); deploying the guide member so at least a distal portion thereof is deployed through an opening in, and disposed in, a chamber, vessel or vein of a body; deflecting the deflectable distal portion with respect to the guide member(view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 27, Lesh discloses the tissue ablating method of claim 26, further comprising the step (s) contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 28, Lesh discloses the tissue ablating method of claim 27, further comprising the step (s) rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 29, Lesh discloses the tissue ablating method of claim 28, further comprising the step (s) of : de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area(view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 30, Lesh discloses the tissue ablating method of claim 28, further comprising the step (s) maintaining the ablation device in an activated condition as the deflectable distal portion is being rotated about the guide member(view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 31, Lesh discloses the tissue ablating method of claims further comprising the step (s) the deflectable distal portion during said rotating so as to maintain the at least a part of the distal portion in contact with the tissues (view figures 3-8, and 16-19; column 24, line 55- column 25, line 20 and column 25, line 40- column 26, line 42).

Regarding claim 37, Lesh discloses a method for ablating tissue in particular atrial tissue, comprising the steps providing a deflection catheter device that includes a deflectable distal portion (12), an ablation device (20) disposed within the deflectable distal portion, a guide member and a guiding mechanism that moveably retains at least a portion of the guide member(3,4-guidewires, and 30,40 guidwire tracking members); localizing an end of the deflectable distal portion with respect an opening in a chamber, vessel or vein of a mammalian body; deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the chamber, vessel or vein of the mammalian body; deflecting the

deflectable distal portion with respect to the guide member; contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 38, Lesh discloses the tissue ablating method of claim 37, further comprising the step (s) of : rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 39, Lesh discloses the tissue ablating method of claim 38, further comprising the step (s) of : de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area (view figures 3-8, and 16-19; column 24, line 55- column 25, line 20 and column 25, line 40- column 26, line 42).

Regarding claim 40, Lesh discloses the tissue ablating method of claim 38, further comprising the step (s) of : maintaining the ablation device in an activated condition as the deflectable distal portion is being rotated about the guide member (view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 41, Lesh discloses the tissue ablating method of claim 38, further comprising the step (s) re-configuring the deflectable distal portion during said rotating so as to maintain the at least a part of the distal portion in contact with the tissues(view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 73, Lesh discloses the method of claim 37 further comprising the steps monitoring electrical conduction signals along a pulmonary vein; identifying an origin of atrial arrhythmias as being located in the pulmonary vein based upon the monitored conduction signals (column 22, lines 40-67).

Regarding claim 46, Lesh discloses a method for treating arrhythmias, comprising the steps providing a deflection catheter device that includes a deflectable distal portion(12), an ablation device(20) disposed within the deflectable distal portion and a guide member (3,4 guidewires); deploying the guide member so at least a distal portion thereof is deployed through an opening in, and disposed in, a vein of a mammalian body; deflecting the deflectable distal portion with respect to the guide member(view figures 3-8, and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 47, Lesh discloses the method of claim 46, further comprising the step (s) of: contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view figures 3-8 and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 48, Lesh discloses the tissue of claim 47, further comprising the step (s) rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area (view figures 3-8; column 24, line 55- column 25, line 20).

Regarding claim 49, Lesh discloses the method of claim 48, further comprising the step (s) de-activating the ablation device during said rotating; and activating the

ablation device after contacting said another tissue area (column 25, line 40- column 26, line 42).

Regarding claim 57, Lesh discloses a method for treating arrhythmias, comprising the steps of : providing a deflection catheter device that includes a deflectable distal portion (12), an ablation device (20) disposed within the deflectable distal portion, a guide member and a guiding mechanism that moveably retains at least a portion of the guide member(3,4-guidewires, and 30,40 guidewire tracking members); localizing an end of the deflectable distal portion within the left atrium of a mammalian body and with respect to an opening in a vein; deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the vein; deflecting the deflectable distal portion with respect to the guide member; contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device(view figures 3-8; column 24, line 55- column 25, line 20).

Regarding claim 58, Lesh discloses the method of claim 57, further comprising the step (s) of: rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area(view figures 3-8 and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 59, Lesh discloses the method of claim 58, further comprising the step (s) de-activating the ablation device during said rotating; and activating the

ablation device after contacting said another tissue area (view figures 3-8 and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 60, Lesh discloses the method of claim 58, further comprising the step (s) of: maintaining the ablation device in an activated condition as the deflectable distal portion is being rotated about the guide member (view figures 3-8 and 16-19; column 24, line 55- column 25, line 20 and column 25, line 40- column 26, line 42).

Regarding claim 65, Lesh discloses a method for treating left atrial arrhythmia in a left atrium of a mammalian body; comprising the steps of: providing a deflection catheter device that includes a deflectable distal portion (view figure 3, 12), an ablation device(20) disposed within the deflectable distal portion, a guide member and a guiding mechanism (3,4-guidewires, and 30,40 guidewire tracking members) that moveably retains at least a portion of the guide member; introducing a portion of the catheter device including the deflectable distal portion into the left atrium; positioning an end of the deflectable distal portion with respect to an a pulmonary vein extending from the left atrium; deploying the guide member from the guiding mechanism so at least a distal portion thereof is deployed through the opening in, and is disposed in, the pulmonary vein(83,84); deflecting the deflectable distal portion with respect to the guide member; contacting a tissue area including tissues to be ablated with at least a part of the deflectable portion, where the ablation device is disposed within the part; and actuating the ablation device (view figures 3-8; column 24, line 55- column 25, line 20).

Regarding claim 66, Lesh discloses the method of claim 65, further comprising the step (s) rotating the deflectable distal portion about the guide member; and wherein said contacting includes contacting another tissue area(column 24, line 55- column 25, line 20 and column 25, line 40- column 26, line 42).

Regarding claim 67, Lesh discloses the method of claim 66, further comprising the step (s) de-activating the ablation device during said rotating; and activating the ablation device after contacting said another tissue area(view figures 3-8 and 16-19; column 24, line 55- column 25, line 20).

Regarding claim 68, Lesh discloses the method of claim 66, further comprising the step (s) of: maintaining the ablation device in an activated condition as the deflectable distal portion is being rotated about the guide member(view figures 3-8 and 16-19; column 24, line 55- column 25, line 20).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Scott whose telephone number is (571)270-7103. The examiner can normally be reached on Monday thru Thursday, 8:00 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3739

/Thomas J Sweet/
Supervisory Patent Examiner, Art Unit 3739